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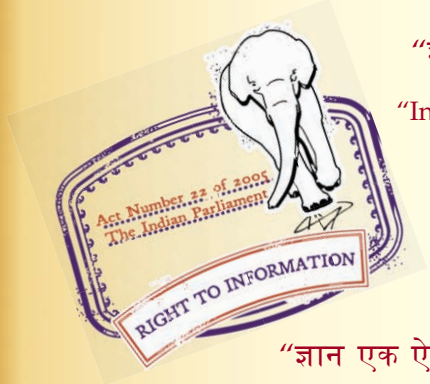

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SPECIFICATION FOR PHENOXYACETIC ACID

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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Indian Standard

SPECIFICATION FOR PHENOXYACETIC ACID

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SPECIFICATION FOR PHENOXYACETIC ACID

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 2 November 1972, after the draft finalized by the Organic Chemicals (Miscellaneous) Sectional Committee had been approved by the Chemical Division Council.

0.2 Phenoxyacetic acid also known as phenoxyethanoic acid, *o*-phenylglycolic acid, phenyl ether glycolic acid and phenylium, is mainly used in the manufacture of antibiotics.

0.3 This specification is based on data and information supplied by Hindustan Antibiotics Ltd, Poona and National Chemical Laboratory, Poona.

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS:2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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1. SCOPE

1.1 This standard prescribes the requirements, methods of sampling and test for phenoxyacetic acid intended for use in the manufacture of antibiotics.

2. REQUIREMENTS

2.1 Description — The material shall be white lustrous crystals and free flowing.

2.2 The material shall also comply with the requirements given in Table 1 when tested according to the methods given in Appendix A. Reference to the relevant clauses of Appendix A is given in col 4 of the table.

*Rules for rounding off numerical values (*revised*).

TABLE 1 REQUIREMENTS FOR PHENOXYACETIC ACID

(*Clause* 2.2)

Sl No.	Characteristic	Requirement	Method of Test (Ref to Cl No. in Appendix A)
(1)	(2)	(3)	(4)
i)	Assay (as phenoxyacetic acid), percent by mass, *Min*	98	A-2
ii)	Melting point	98 to 100°C	A-3
iii)	Moisture, percent by mass, *Max*	1	A-4
iv)	Heavy metals (as Pb) ppm, *Max*	10	A-5
v)	Arsenic (as As) ppm, *Max*	10	A-6

3. PACKING AND MARKING

3.1 The material shall be packed, stored and transported in mild steel, plywood or fibre drums with polyethylene or other suitable lining or as agreed to between the purchaser and the supplier.

3.2 Each container shall be marked with the following:

a) Name of the material;

b) Name of the manufacturer or his recognized trade-mark, if any;

c) Net mass of the contents; and

d) Lot or batch number, in code or otherwise.

3.2.1 The containers may also be marked with the Standard Mark.

NOTE — The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

4. SAMPLING

4.1 Representative samples of the material shall be drawn and their conformity shall be judged as prescribed in Appendix B.

APPENDIX A

(*Clause* 2.2)

METHODS OF TEST FOR PHENOXYACETIC ACID

A-1. QUALITY OF REAGENTS

A-1.1 Unless specified otherwise, pure chemicals and distilled water (*see* IS : 1070-1960*) shall be employed in tests.

NOTE — 'Pure chemicals' shall mean chemicals that do not contain impurities which affect the results of analysis.

A-2. ASSAY OF PHENOXYACETIC ACID

A-2.1 Reagents

A-2.1.1 *Rectified Spirit* (*see* IS : 323-1959†) — neutralized to phenolphthalein indicator.

A-2.1.2 *Phenolphthalein Indicator* — Dissolve 0·1 g of phenolphthalein in 100 ml of 60 percent rectified spirit.

A-2.1.3 *Standard Sodium Hydroxide Solution* — 1 N.

A-2.2 Procedure — Weigh accurately about 5 g of the material into a 250-ml conical flask. Dissolve in about 50 ml of rectified spirit and titrate with standard sodium hydroxide solution using phenolphthalein as indicator.

A-2.3 Calculation

$$\text{Phenoxyacetic acid, percent by mass} = \frac{15{\cdot}21\ VN}{M}$$

where

V = volume in ml of standard sodium hydroxide solution used,

N = normality of standard sodium hydroxide solution, and

M = mass in g of the material taken for the test.

A-3. DETERMINATION OF MELTING POINT

A-3.1 Procedure — Carry out the determination according to the method prescribed in IS : 5762-1970‡.

*Specification for water, distilled quality (*revised*).

†Specification for rectified spirit (*revised*).

‡Method for determination of melting point and melting range.

A-4. DETERMINATION OF MOISTURE

A-4.1 Apparatus

A-4.1.1 *Glass Weighing Bottle* — squat form (*see* IS:1574-1960*).

A-4.1.2 *Vacuum Oven* — capable of maintaining a temperature of 60 ± 1°C.

A-4.2 Procedure — Weigh the glass weighing bottle which has been previously dried by heating to 100°C and cooled in a desiccator. Transfer about 5 g of the material into the weighing bottle and again weigh. Dry the material at 60°C under vacuum not exceeding 5 mm of Hg till constant mass (generally it takes four hours). At the end of the drying period, stopper and cool the weighing bottle in a desiccator and weigh.

A-4.3 Calculation

$$\text{Moisture, percent by mass} = \frac{100\ (M_1 - M_2)}{(M_1 - M_3)}$$

where

M_1 = mass in g of the glass weighing bottle with the material,

M_2 = mass in g of the glass weighing bottle with the dried material, and

M_3 = mass in g of the glass weighing bottle.

A-5. TEST FOR HEAVY METALS

A-5.0 Outline of the Method — The colour produced by heavy metals with hydrogen sulphide is compared with that produced by standard lead solution under identical conditions.

A-5.1 Apparatus

A-5.1.1 *Nessler Cylinders* — 50-ml (*see* IS:4161-1967†).

A-5.2 Reagents

A-5.2.1 *Dilute Acetic Acid* — 1:1 (v/v) dilute acetic acid which complies with the following additional tests:

Evaporate 20 ml of the acid in porcelain dish nearly to dryness on a steam-bath. Add to the residue 2 ml of the acetic acid and dilute with water to 25 ml. Then add 10 ml of a solution of hydrogen sulphide. Any dark colour produced shall not be darker than a control made with 0·04 mg of lead and 2 ml of the diluted acetic acid (2 parts per million).

*Specification for glass weighing bottles.
†Specification for Nessler cylinders.

A-5.2.2 *Hydrogen Sulphide Solution* — A freshly prepared saturated solution of hydrogen sulphide in water.

A-5.2.3 *Stock Lead Nitrate Solution* — Dissolve 159·8 mg of lead nitrate in 100 ml of water to which 1 ml of nitric acid has been added, then dilute to 1 000 ml with water.

NOTE — This solution shall be prepared and stored in glass containers free from solution of lead salts.

A-5.2.4 *Standard Lead Solution* — Dilute 10 ml of the stock solution of lead nitrate accurately to 100 ml with water. This solution shall be freshly prepared. Each millilitre of this standard lead solution contains the equivalent of 0·01 mg of lead. When 1 ml of standard lead solution is employed to prepare the solution to be compared with a solution of 1 g of the substance being tested, the comparison solution thus prepared contains the equivalent of 10 parts of lead per million parts of the substance being tested.

A-5.2.5 *Solution A* — Weigh 4·0 g of the material and transfer to a Nessler cylinder. Dissolve in about 10 to 15 ml of acetic acid and dilute to 40 ml and mix.

A-5.2.6 *Solution B* — Place in another cylinder that matches with the one used above, 2 g of the sample. Dissolve in 10 to 15 ml of acetic acid, add 2 ml of standard lead nitrate solution (contains 0·01 mg lead/ml) and dilute to 40 ml and mix.

A-5.3 Procedure — To each of the cylinder containing Solution A and Solution B add 10 ml of hydrogen sulphide solution and mix. Allow to stand for 5 minutes. View downward over white surface.

A-5.3.1 The limit for heavy metal shall be taken as not having been exceeded if the intensity of the colour produced in the test with Solution A is not greather than that produced in the test with Solution B.

A-6. TEST FOR ARSENIC

A-6.0 Outline of the Method — The stain produced by arsenic on a mercuric chloride paper is compared to stains produced by arsenic solution.

A-6.1 Reagent

A-6.1.1 *Acetic Acid*

A-6.2 Procedure — Dissolve 1 g of the material in 5 ml of acetic acid in a 'gutzeit bottle' and proceed as prescribed in IS:2088-1962* using 13·3 ml of arsenic trioxide solution.

*Modified Gutzeit method of test for arsenic.

APPENDIX B

(*Clause* 4.1)

SAMPLING OF PHENOXYACETIC ACID

B-1. GENERAL REQUIREMENTS OF SAMPLING

B-1.1 Samples shall be taken at a place protected from damp air, dust and soot.

B-1.2 Sampling instrument shall be clear and dry.

B-1.3 Precaution shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-1.4 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-1.5 The samples shall be placed in clean, dry and air tight glass containers or other suitable containers on which the material has no action.

B-1.6 The sample containers shall be of such a size that they are almost completely filled by the sample.

B-1.7 Each sample container shall be sealed air tight after filling and marked with full details of sampling, the date of sampling, batch number and important particulars of the consignment (*see also* **3.2**).

B-1.8 Samples shall be stored in a cool and dry place.

B-2. SAMPLING INSTRUMENT

B-2.1 The sampling instrument is a closed type sampling tube, undivided (*see* Fig. 1). It consists of two concentric cylindrical tubes made of a metal which is not affected by the material being sampled (preferably of stainless steel), one closely fitting into the other throughout their length so that it is possible to rotate one tube within the other, a suitable handle being provided for the purpose. Longitudinal openings of about one-third the circumference are cut in both tubes throughout their length. In one position the two openings coincide and admit the material into the hollow inner tube. By rotating the inner tube through 180° the opening is tightly closed and a 'core' of material being enclosed therein may be withdrawn. This type of sampler is usually provided with a locking arrangement so that the tubes are held together in any desired position. The outer tube is provided with a sharp conical end to facilitate penetration but the base of the cone shall be closed so that no material is entrapped in this portion. The height of the cone shall be equal to its base diameter.

The whole instrument shall be of sufficient length to penetrate an entire diagonal of the container being sampled. The diameter of the inner cylindrical space may vary from 20 to 40 mm, proportionately to the length. A length of 150 cm and a diameter of 30 mm can cater for most needs.

B-2.1.1 *Use of Sampling Instrument* — The instrument is inserted in closed position in oblique direction till it touches bottom. The material is admitted by rotating and opening the tubes and finally closing them, withdrawing the sample in this process. In case the minimum quantity of material required for test from each container is more than the capacity of the instrument, further 'cores' shall be taken from different parts of the same container such that they are at least 75 mm in the case of drums, bags, etc, and 25 mm in the case of small containers, from the wall of the container. In all cases the instrument shall be inserted till it touches bottom so that an entire cross-section is withdrawn.

B-3. SCALE OF SAMPLING

B-3.1 Lot — All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of containers pertaining to different batches of manufacture, the containers belonging to the same batch of manufacture shall be grouped together and each such group shall constitute a separate lot.

B-3.2 For ascertaining the conformity of the lot to the requirements of this specification, tests shall be carried out for each lot separately. The number of containers to be selected for drawing the sample shall depend upon the size of the lot and shall be in accordance with Table 2.

TABLE 2 NUMBER OF CONTAINERS TO BE SELECTED FROM LOTS OF DIFFERENT SIZES

Lot Size (N)	No. of Containers to be Selected (n)
4 to 25	3
26 ,, 50	4
51 ,, 100	5
101 ,, 150	6
151 ,, 300	7
301 and above	8

NOTE — When the size of the lot is three or less, all the containers shall be sampled.

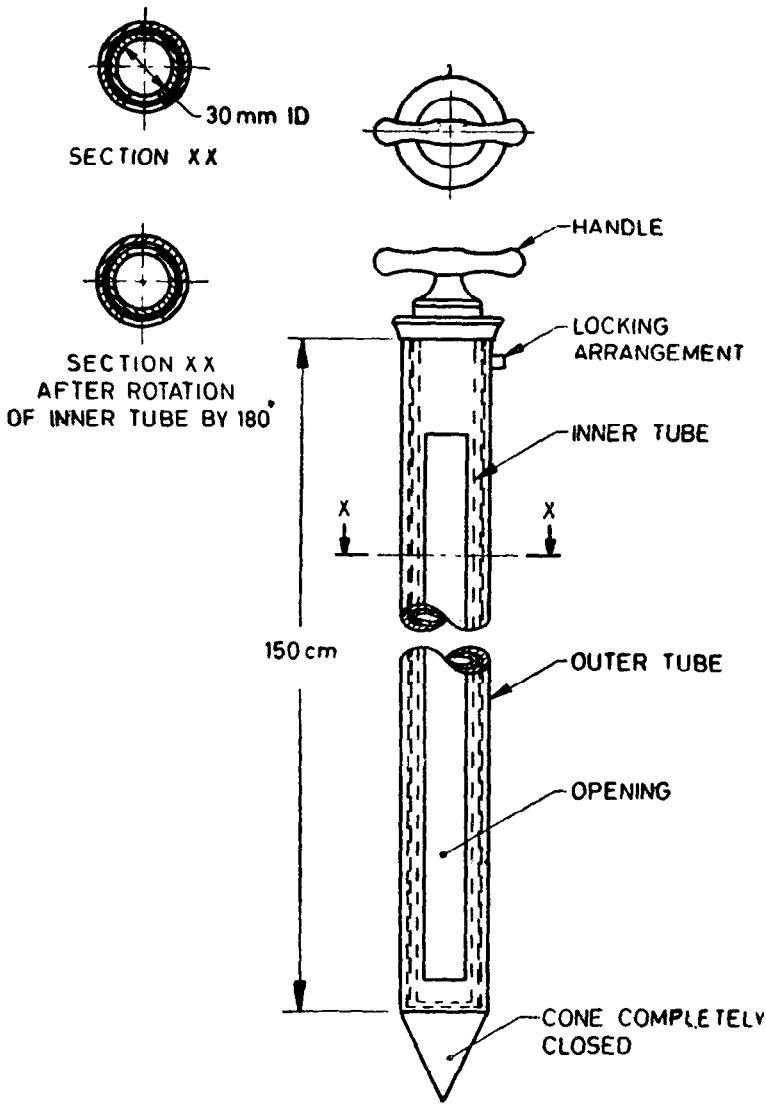

FIG. 1 CLOSED TYPE SAMPLING TUBE, UNDIVIDED

B-3.3 The containers shall be selected at random from the lot and to ensure the randomness of selection, random number tables shall be used. In case such tables are not available, the following procedure may be adopted:

Starting from any container, count them in one order as 1, 2, 3,..., up to r, and so on, where r is the integral part of N/n (N being the lot size and n the number of containers to be selected). Every rth container thus counted shall be withdrawn to give sample for test.

B-4. TEST SAMPLE AND REFEREE SAMPLE

B-4.1 From each of the containers selected as in **B-3.2**, draw with the sampling instrument of an appropriate size small portions of the material from different parts of the container. The total quantity so drawn from each of the containers shall be approximately equal to thrice the quantity required for testing purposes.

B-4.2 Mix thoroughly all the portions of the material drawn from the same container to give a representative sample for the container.

B-4.3 From the samples (*see* **B-4.2**) representing different containers selected in **B-3.2**, a small but equal quantity of material shall be taken and thoroughly mixed to form a composite sample of about 600 g. The composite sample so obtained shall be divided into three equal parts, one for the purchaser, another for the supplier and third for the referee.

B-4.4 The remaining portion of the material in the samples (*see* **B-4.2**) from different containers shall be divided into three equal parts, each forming an individual sample. One set of individual samples representing the n containers selected shall be for the purchaser, another for the supplier and the third for the referee.

B-4.5 All the individual and composite samples shall be transferred to separate containers. These containers shall then be sealed air-tight with stoppers and labelled with full identification particulars given in **B-1.7**.

B-4.6 The referee samples consisting of a composite sample and a set of n individual samples, shall bear the seals of both the purchaser and supplier and shall be kept at a place agreed to between the two. This shall be used in case of any dispute between the two.

B-5. TESTS

B-5.1 Tests for description, determination of assay and melting point shall be conducted on each of the individual samples.

B-5.2 Tests for other characteristics shall be conducted on the composite sample.

B-6. CRITERIA FOR CONFORMITY

B-6.1 For Individual Samples — The lot shall be declared as conforming to the requirements of description, assay and melting point if each of the test results satisfies the corresponding requirements prescribed in this standard.

B-6.2 For Composite Sample — For declaring the conformity of a lot to the requirements of all other characteristics tested on the composite sample, the test results shall satisfy the relevant requirements prescribed in this standard.

BUREAU OF INDIAN STANDARDS

Headquarters :

Manak Bhavan, 9 Bahadur Shah Zafar Marg, NEW DELHI 110002

Telephones : 3 31 01 31, 3 31 13 75 Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices :	*Telephone*
*Western ; Manakalaya, E9 MIDC, Marol, Andheri (East), BOMBAY 400093	6 32 92 95
†Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola, CALCUTTA 700054	36 24 99
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